

Wound dressing

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
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Abstract of GB2370226

A wound dressing having anti-microbial activity comprises a first fibre capable of bonding with silver (1) cations. The wound dressing comprises a blend of the first fibre to which silver (1) cations are bonded and a second fibre which is substantially free from silver. The wound dressing comprises from 0.01 to 5.0 percent by weight of silver (1) cations, based on the weight of fibre.

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(56) Documents Cited

GB 2272641 A

EP 0905289 A2

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WO 96/13282 A1

US 6087549 A

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(54) Abstract Title

Wound dressing

(57) A wound dressing having anti-microbial activity comprises a first fibre capable of bonding with silver (1) cations. The wound dressing comprises a blend of the first fibre to which silver (1) cations are bonded and a second fibre which is substantially free from silver. The wound dressing comprises from 0.01 to 5.0 percent by weight of silver (1) cations, based on the weight of fibre.

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WOUND DRESSING

This invention relates to a wound dressing, in particular to a wound dressing having antimicrobial activity.

International Patent Applications WO 93/12275, WO 94/16746 and PCT/GB99/02093
5 disclose the carboxymethylation of lyocell fibre and the use of such carboxymethylated fibre in wound dressings.

European Patent Application No. 707,793 discloses a silver-containing antimicrobial agent which comprises carboxymethylcellulose containing silver in an amount of 0.02 to 1 percent by weight and having a degree of substitution of at least 0.4.

10 Japanese Published Unexamined Patent Application 11-001,895 discloses a hygienic product such as a disposable diaper, sanitary napkin or incontinence pad which comprises water-insoluble carboxymethylcellulose (derived from woodpulp) containing 0.32% by weight silver ions.

The silver-containing fibre used in the prior art dressings discolour (turn dark brown or
15 black) on exposure to light. In consequence, such dressings may exhibit an unsightly appearance. Attempts have been made to overcome this problem and are described for example in International Patent Application WO 00/90173.

It is an object of the present invention to provide a wound dressing in which the above disadvantages are reduced or substantially obviated.

The present invention provides a wound dressing having anti-microbial activity, which comprises a first fibre capable of bonding with silver (I) cations, characterised in that the wound dressing comprises a blend of the first fibre to which silver (I) cations are bonded and a second fibre which is substantially free from silver.

The wound dressing according to the invention preferably comprises from 0.01 to 5.0, more preferably from 0.1 to 4, even more preferably from 0.5 to 3, most preferably 1 to 2 percent by weight based on the weight of fibre, of silver(I) cations.

- 5 The first fibre is preferably substantially insoluble in water and preferably comprises a sodium carboxymethylcellulose fibre, an alginate fibre, a chitosan or chitosan derivative fibre or an acrylic fibre. Where the fibre is a carboxymethylcellulose fibre, it preferably has a degree of substitution between 0.1 and 0.4. Where the fibre is an acrylic fibre, it is preferably an acrylic fibre which incorporates a comonomer such as itaconic acid or 2-acrylamido
10 methyl propane sulphonic acid to provide dye-sites in the fibre.

- Wound dressings in which the first fibre is a carboxymethylcellulose fibre are particularly preferred. The second fibre may be similar or different to the first fibre. Similar fibres are preferably used. The second fibre should be such as not to discolour to an objectionable degree in light, and as such should, for example, contain no silver or such low levels of silver
5 that it does not discolour at all or discolours only to an degree which is not objectionable aesthetically.

The ratio of the first silver-containing fibre to the second fibre is preferably in the range from 0.5 to 25% by weight, more preferably 5 to 20% by weight, of the total weight of the fibre

- In order to achieve the desired overall concentration of silver ions, the first fibre preferably includes about 10% by weight, based on the weight of fibre, of silver(I) cations and is blended with a large proportion of unsilvered fibre so as to give a blended product containing 1% to 2% by weight of silver. The silver ions are preferably chemically bonded to the first
5 fibre.

As specified above, the degree of substitution (D.S.) of the sodium carboxymethylcellulose (CMC) is preferably at least 0.1, and is preferably less than 0.4. Such CMC is inherently

insoluble in water and also in saline solution. A higher D.S. gives at least partial solubility in water, which is undesirable in the field to which the invention relates. The D.S. is more preferably in the range from 0.20 to 0.35, for example about 0.3.

The silver ions are preferably introduced into the first CMC fibre by ion-exchange, for example by contacting CMC with an aqueous solution of a salt such as, silver(I) nitrate. As CMC often contains sodium chloride as a by product of the reaction between cellulose and chloroacetic acid and as silver chloride is highly insoluble and it may be preferred to perform
5 the ion-exchange reaction on a salt free grade of CMC. It is preferred that the balance of the carboxyl groups in the CMC be neutralised with sodium ions.

The CMC is preferably derived from lyocell, as disclosed for example in WO 93/12275, WO 94/16746 and PCT/GB99/02093.

The fibrous CMC is preferably in the form of staple fibre or continuous filament yarn. It is preferably contained within a textile article such as a woven, knitted or most preferably a nonwoven fabric, such as a needlepunched nonwoven fabric.

The dressings of the invention are preferably gel-forming, which makes them advantageously low-adherent to wounds and consequently easy to remove. They are soft, conformable and absorbent. Silver metal ions are released slowly over an extended period of time from a wetted dressing of the invention.

The second fibre which does not contain silver is preferably also CMC, but other kinds of gel-forming fibre or of textile fibre may also be utilised. If the dressings are blended from unexposed fibre, on exposure to light, such dressings develop either a speckled appearance or a light brown or light grey colour which is not unsightly. However, it is preferred to pre-
5 expose the silver-containing fibre to light before blending, so that after blending the dressing is light stable and the uniformity of blending can be checked visually.

The wound dressings of the invention may contain other medicaments if desired.

The wound dressings of the invention are useful in the treatment of infected wounds, and as a prophylactic measure against infection of uninfected wounds.

The invention is illustrated by the following Example, in which parts and proportions are by weight unless otherwise specified.

EXAMPLE

Manufacture of Master Batch Material

The optimum conditions for manufacture of a master batch material were determined as follows:

Sodium carboxy methyl cellulose fibre (CMC), Hydrocel®, available from Acordis Speciality Fibres Limited of Coventry England, was soaked in silver nitrate (AgNO_3) solution in 50 volume % industrial methylated spirit/50 volume % water and the following table shows the percentage silver take-up after soaking.

% $\text{AgNO}_3 \rightarrow$	4% AgNO_3	8% AgNO_3
Conditions ↓		
15 minutes @ 65°C	8.1	6.1
15 minutes @ ambient	12.6	11.2
4 hours @ ambient	8.0	9.0

From the above results, it was determined that higher concentrations of silver nitrate are not really beneficial and that the use of a solution having a concentration of approximately 4% silver nitrate to produce a fibre having a silver content of 8% would give the optimum results. It was therefore decided to produce the master batch material using such a solution.

CMC tow or staple (50g) was added to a solution of 4% silver nitrate (300g) in industrial methylated spirit /water 50/50 at ambient temperature. The solution was held for

convenience in a round screw top bottle so that it could be rolled on a laboratory bottle roller. The bottle was rolled for 15 minutes whereupon an ion exchange mechanism took place which produced silver containing CMC - referred to herein as silver CMC (8%w/w, Ag).

The excess silver nitrate solution was discarded and replaced with 50/50 industrial methylated spirit/water wash liquor (300g) followed by shaking for five minutes. This washing process was repeated and finally a soft finish was used. This consisted of 0.5% polysorbate 20 (Tween) 20 in 90:10 industrial methylated spirit/water (i.e. 1.5g in 300g).

Excess liquor was squeezed out of the fibre, which was then allowed to dry at ambient temperature. The silver CMC tow was then opened out and spread onto an open bench to allow maximum access to light. The discolouring tow was handled periodically to expose new surfaces to the light. This was continued until the majority of the tow assumed a chocolate brown coloration (about two weeks).

The brown silver CMC tow produced was blended with untreated carboxymethyl cellulose (CMC) fibre at the ratios shown as follows to produce blends having 0.5%, 1.0% and 2.0% silver:

6.25% silver CMC + 93.75% CMC fibre = 0.5% Ag

12.5% silver CMC + 87.50% CMC fibre = 1.0% Ag

25.0% silver CMC + 75.00% CMC fibre = 2.0% Ag

Blending was accomplished by carrying out a carding operation twice to achieve a uniform blend, on hand pre-mixed fibre. The carded web was then cross-folded to give the desired basis weight. The web was then bonded on a needle loom to give a coherent web from which individual dressings were cut. In addition, a conventional carboxymethyl cellulose fibre control sample was manufactured by the same method.

Absorbency Results

The master batch material was produced by the soaking of CMC fibre tow in silver nitrate and the absorbency tests were first of all carried out on tow using a free swell test. It was found that the CMC fibre control had an absorbency of 28g/g and the silver CMC had an absorbency of 30g/g. These differences were not considered to be significant.

Absorbency tests were then carried out on fabric produced by needle felting from fibres as above.

Fabric absorbencies (Petri dish values) were found to be as shown in the following table, in which gsm = grams per square metre and is a measure of the amount of fabric produced.

	gsm	Absorbency g/g	Absorbency g/piece
CMC control	111	16.0	18.0
0.5% silver CMC	99	20.0	19.5
1.0% silver CMC	91	20.5	18.7
2.0% silver CMC	65	22.3	14.5

As can be seen from the above table, the addition of silver was found to have very little effect on the absorbency, if anything increasing the absorbency on a gram per gram basis, though having less effect on absorbency on a gram per piece basis.

After wetting for 30 minutes in saline, the fabrics which were initially a fairly dark fawn, changed colour and became lighter and more translucent as time passed.

It appeared that there was no difference in the gelling properties between the CMC and the silver CMC, which is an important observation in that the silver addition does not destroy the valuable gelling properties.

Microbial Activity

To measure the efficiency of the silver containing material in reducing microbial activity, 250 g of milk was mixed with 0.2 g of fibre. The results were as follows:

Control (milk alone)	Malodour in 2 days
Control (CMC in milk)	Malodour in 2 days
0.5% Silver (web)	Malodour in 2 weeks
8.0% Silver (tow)	No Malodour in 3 weeks

These tests were repeated with 0.9wt% sodium chloride additions (chosen to be equivalent to the salt level in body fluids) to the milk, and the same results were obtained. This shows that the chloride ions in the salt were not detrimental to the antimicrobial properties of the silver in the silver CMC.

As can be seen from the above results, milk alone and milk containing CMC fibre alone went off in two days, as could be easily determined by the smell. By comparison, where the web contained 0.5% silver, there was a two week period before the milk went off and could be smelt. With unblended tow containing 8% silver, no smell could be detected after a three week period when the test was stopped.

In practice, the wound treatment products utilising the invention are unlikely to be left on a wound for more than a few days, and certainly no more than a week, so that it can be seen that a blend containing 0.5% silver retains its efficiency in terms of antimicrobial effect for at least twice the period that would be required in practice.

The invention also contemplates multiple layer dressings some or all of which layers may comprise blended product incorporated silver additions. For example, a silver containing blended layer of a non-gel forming fibre, such as a silver containing acrylic fibre blended with pure acrylic fibre could be faced with a wound contact layer of a gel forming fibre. An example of the contact layer could be an alginate fibre and the alginate layer could be blended with a silver added fibre or may have no silver at all, being a simple gel forming alginate fibre.

CLAIMS

1. A wound dressing having anti-microbial activity, which wound dressing comprises a first fibre capable of bonding with silver (I) cations, characterised in that the wound dressing comprises a blend of the first fibre to which silver (I) cations are bonded and a second fibre which is substantially free from silver.
2. A wound dressing according to claim 1 characterised in that it comprises from 0.01 to 5.0 percent by weight, based on the weight of fibre, of silver(I) cations.
3. A wound dressing according to claim 2 characterised in that it comprises from 0.1 to 4.0 percent by weight based on the weight of fibre, of silver(I) cations.
4. A wound dressing according to claim 3 characterised in that it comprises from 0.5 to 3.0 percent by weight based on the weight of fibre, of silver (I) cations.
5. A wound dressing according to claim 3 characterised in that it comprises from 1.0 to 2.0 percent by weight based on the weight of fibre, of silver(I) cations
6. A wound dressing according to any of claims 1 to 5 characterised in that the first fibre is substantially insoluble in water
7. A wound dressing according to any of claims 1 to 6 characterised in that the first fibre comprises a carboxymethylcellulose fibre, an alginate fibre, a chitosan or chitosan derivative fibre or an acrylic fibre.
8. A wound dressing according to claim 7 characterised in that the first fibre is a carboxymethylcellulose fibre which has a degree of substitution between 0.1 and 0.4.
9. A wound dressing according to claim 7 characterised in that the first fibre is an acrylic

fibre which incorporates a comonomer to provide dye-sites in the fibre.

10. A wound dressing according to claim 9 characterised in that the comonomer is itaconic acid or 2-acrylamido methyl propane sulphonic acid.
11. A wound dressing according to any of claims 1 to 10 characterised in that the first fibre and the second fibre are similar.
12. A wound dressing according to any of claims 1 to 11 characterised in that the ratio of the first fibre to the second fibre is in the range of from 0.5 to 25% by weight of the total weight of the fibre.
13. A wound dressing according to claim 12 characterised in that the ratio of the first fibre to the second fibre is in the range of from 5 to 20% by weight of the total weight of the fibre.
14. A wound dressing according to any of claims 1 to 9 characterised in that the first fibre includes about 10% by weight, based on the weight of fibre, of silver(I) cations.
15. A wound dressing according to any of claims 1 to 11 characterised in that the silver ions are preferably chemically bonded to the first fibre.
16. A wound dressing according to any of claims 7 to 12 characterised in that the first fibre is a carboxymethylcellulose fibre and the degree of substitution is in the range from 0.20 to 0.35
17. A wound dressing according to claim 13 characterised in that the degree of substitution is about 0.3.
18. A wound dressing according to any of claims 1 to 14 characterised in that the silver ions are introduced into the first fibre by ion-exchange.

19. A wound dressing according to any of claims 1 to 15 characterised in that the first fibre is a carboxymethylcellulose fibre and the carboxymethylcellulose is derived from lyocell.
20. A wound dressing according to any of claims 1 to 16 characterised in that the fibrous carboxymethylcellulose is in the form of a staple fibre or continuous filament yarn.
21. A wound dressing according to any one of the preceding claims characterised in that the carboxymethylcellulose is present in a needlepunched nonwoven textile.
22. A wound dressing substantially as herein described and with reference to the Example.



INVESTOR IN PEOPLE

Application No: GB 0023155.5
Claims searched: 1-22

Examiner: Dr Jeremy Kaye
Date of search: 23 February 2001

Patents Act 1977 Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.S): A5R (RBA, RBBA, RPF, RPD, RPG, RPR)

Int Cl (Ed.7): A61L 15/44

Other: Online: EPODOC, WPI, PAJ

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
A	GB 2272641 A (TOAGOSEI CHEMICAL)	1
Y	EP0905289 A2 (NAKAMURA) col.4 ll.1-22; col.5 ll.37-54; col.6 ll.5-16	1
Y	WO 98/09590 A1 (BRISTOL-MYERS SQUIB) p.1 l.32 - p.5 l.12;	1
A	WO 96/13282 A1 (INNOVATIVE TECHNOLOGIES)	1
X,Y	US 6087549 (FLICK) col.4 ll.20-33; col.5 ll.1-6; col.6 ll.11-67;	1

X Document indicating lack of novelty or inventive step
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